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The Peroxide Company

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Pergan Marshall, LLC
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August 06, 2012

TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004Cc: Akzo Nobel Polymer Chemicals bv
Arkema France
United Initiators GmbH & Co. KG**SUBJECT: TSCA 8(e) Notice**

Dear TSCA Section 8(e) Coordinator:

On behalf of Pergan Marshall LLC we are submitting final histopathological results of an oral 28-day study of an OECD 407 Repeated Dose 28-Day Oral Toxicity Study in rats with bis(3,5,5-trimethylhexanoyl)peroxide (CAS 3851-87-4) 75% in isododecane (CAS 93685-81-5), as stabiliser. The study was sponsored by Pergan GmbH.

Groups of ten rats (five females and five males) were dosed at 100, 300 and 1000 mg/kg bw by oral gavage. The test substance was dissolved in *Paraffinum perliquidum*. A control group received *Paraffinum perliquidum* alone.

All animals survived the treatment period. At terminal sacrifice, the incidence of pale liver observation was increased in a dose-related manner in groups treated at 300 and 1000 mg/kg/day, and pale and enlarged kidney was found in one male treated at 300 mg/kg/day. Pale liver was observed in 3/5 males and 1/5 females treated at 300 mg/kg/day and in 5/5 males and 2/5 females treated at 1000 mg/kg/day. This finding corroborated the higher liver weights recorded in these groups (males: $p < 0.001$ at 300 and 1000 mg/kg/day; females: $p < 0.01$ at 1000 mg/kg/day). In view of the organ weight and histological findings seen, these observations were considered test item-related.

Histopathological findings considered to be test item-related were seen in the liver, kidney, seminal vesicle, coagulating gland and thymus. The kidney changes were considered to be of no toxicological relevance for humans.

In the liver, minimal or mild diffuse hepatocellular hypertrophy was noted in a dose-related manner in both sexes treated at 300 and 1000 mg/kg/day. A minimal to moderate diffuse hepatocellular microvacuolation was observed in the same groups, without being dose-related, and also in 1/5 female treated at 100 mg/kg/day. In addition, in males treated at 1000 mg/kg/day, a minimal degree of hepatocellular single cell death (mainly in the centrilobular zones of hypertrophy) was seen.

In the kidney of males only, hyaline droplets in corticotubular cells were seen in a dose related manner in the groups treated at 100, 300 and 1000 mg/kg/day. These were considered to represent $\alpha 2$ -microglobulin. They were associated with multifocal debris-filled tubules in the inner cortex and with diffuse dilation of medullary tubules, considered to be most likely the consequence of excretion of degenerated and exfoliated corticoepithelial cells. Furthermore, at 300 and 1000 mg/kg/day in males, minimal multifocal corticotubular degeneration was also observed. As the renal storage of $\alpha 2$ -microglobulin is commonly recognized to be a male rat-specific event, its test item-related increase in severity and associated secondary renal changes in this study are regarded to be of no relevance for man.

**CONTAINS NO CB**

At 1000 mg/kg/day, in the seminal vesicle and coagulating gland, the incidence of epithelial single cell death was increased, and in the thymus, in both sexes and confirming minor weight decreases, a minimal tendency towards more prominent atrophy/regression was noted.

Other parameters measured in the study have not yet been analysed.

Please contact me at 903-934-7757 if you have any questions regarding this letter.

Sincerely,

Jan Fulton

Jan Fulton

From: (903) 938-5141
 Donna Sellers
 Pergan Marshall, LLC
 710-B BUSSEY ROAD

MARSHALL, TX 75670

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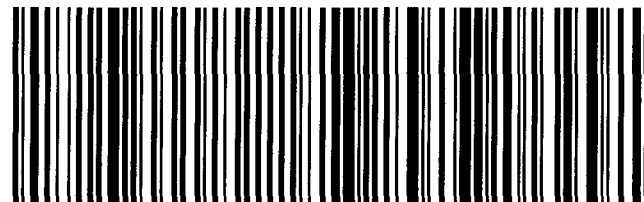
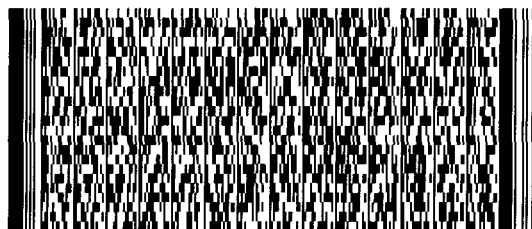
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